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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,446	12/16/2003	Thomas D. Kelly	DI-5928 (112713-457)	8102

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EXAMINER
DEAK, LESLIE R

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,446	KELLY ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 39-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 99-107 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant's new claims represent various subcombinations of the originally claimed device that does not recite all the limitations of the previously presented combination. In particular, the new claims add limitations drawn to a plurality of valves and a balance, but are silent with regard to the control scheme recited in the originally examined claims. As such, the claims are related inventions that are patentably distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 99-107 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 14-20, 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,470,483 to Bene et al.

In the specification and figures, Bene discloses the device as claimed by applicant. IN particular, Bene discloses a device for controlling the balance of fluid in an extracorporeal circuit with a fluid flow path 6, 7, with a medical fluid supply 10, a first pump 11 that adds fluid to the circuit, a blood filtration unit 2, second pump 12 that pulls fluid from the filter, a bypass line 15 that isolates fluid flow from the filtration unit, and a programmable controller 30 (see FIG 1, column 2, lines 33-67). The controller may adjust operation of the pumps and the clamps as required by the system (see column 3, lines 30-40, column 4, lines 60-65), thus rendering the Bene device "operable to," or capable of being operated, in the manner claimed by applicant.

With regard to claim 14, Bene specifically discloses that the disclosed device may isolate the filtering device from the patient in the extracorporeal circulation loop (see column 3, lines 28-35), and that a bolus pump 11 may deliver a quantity or bolus of substitute liquid to the patient during therapy (see column 3, lines 15-22). Bene further discloses that the device is suitable for hemofiltration of hemodiafiltration.

With regard to claims 16-18, applicant sets forth limitations drawn to the operation of the claimed device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, Bene discloses that the device is controlled by a controller that has a set delivery rate that is established at the outset of treatment (see column 3, lines 5-10), and that the operation of the system may be adjusted to control for variations in operation (see column 3, lines 50-60). These

disclosures indicate that the device is capable of receiving the data claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 19 and 20, the amount of fluid injected into the patient or the length of time of the bypass mode is determined, in part by sensor 19. Sensor 19 is disclosed as providing pressure measurements, but is not limited to pressure measurements. Bene specifically discloses that a graphic recording device in communication with the controller and the circulation system may illustrate a fluid delivery rate deviation of 50mL/hr, indicating that the device comprises blood flow volume sensor, as claimed by applicant (see column 4, lines 60-67, column 5, lines 1-4).

With regard to claims 33-37, Bene discloses that the device is suitable for hemofiltration of hemodiafiltration and illustrates clamps 17 and 18 upstream and downstream of filter 2. The device further includes valve 16 that would allow fluid to bypass the filtration device. By operating clamps 16 and 18, the medical fluid supply 10 may be delivered upstream or downstream of the blood filtering device 2, and the blood filtering device removes ultrafiltrate from the circuit upstream of the medical fluid entry point. Applicant claims that various parts of the device are "operable" to perform a particular function. Such language fails to positively claim the function desired by applicant, and the limitations are regarded as a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In

the instant case, the Bene device and valves are in locations that allow for the delivery of fluids at the locations set forth by applicant, thereby meeting the limitations of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,470,483 to Bene et al in view of US 6,830,553 to Burbank et al.

In the specification and figures, Bene discloses the device substantially as claimed by applicant, with the exception of various operative modes of the device. Burbank discloses a blood treatment system in which the various pumping, clamping, and sensing devices on the machine provide fluid management and safety controls by sensing pressure air, temperature. The machine provides other functions, such as priming, supplying a replacement fluid bolus, and rinseback of the person's blood.

With regard to claims 21-26, the device disclosed by Burbank performs a rinseback operation at the end of therapy, which is initiated by the controller at the end of the therapy or by the operator (see column 24, lines 40-67, column 31, lines 15-60). It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art

apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, Burbank discloses that the device is capable of receiving operator input at any time during the therapy session, indicating that the device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claims 27-32, the device disclosed by Burbank performs a prime operation before therapy to remove air, which is initiated by the controller at the beginning of the therapy or by the operator (see column 24, lines 18-38, column 31, lines 15-60). It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, Burbank discloses that the device is capable of receiving operator input at any time during the therapy session, indicating that the device is capable of operating as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claim 38, Burbank discloses that the device comprises a safety system including a temperature sensor (see column 6, lines 35-47). The safety system comprises an alarm system which may allow the operator to stop the pumps if the sensed conditions vary from preset ranges (see column 26, lines 5-30), meeting the limitations of the claims.

The Burbank device is designed to provide automated and sterile control of a hemofiltration operation that makes frequent hemofiltration more convenient for patients and operators (see column 4, lines 48-59, column 6, lines 35-56). Therefore, it would

have been obvious to one having ordinary skill in the art at the time the invention was made to program the controller of the Bene device to perform operator-directed or automatic control of bolus delivery, rinseback, alarm, and priming operations, as taught by Burbank, in order to provide an automated system that makes frequent hemofiltration more sterile and convenient for the patient and operator, as taught by Burbank.

Response to Arguments

6. Applicant's amendment, including replacement drawings, dated 6 July 2006, has been entered and considered.

7. Applicant's arguments filed 6 July 2006 have been fully considered but they are not persuasive.

8. Applicant argues that the Bene reference does not disclose a medical fluid flow path and an extracorporeal circuit, and an apparatus operable to isolate the blood filtering device from the medical fluid flow path. Bene illustrates blood circuit 6.7, and medical fluid flow path 10 (supply bag 11, drip chamber 9). Pump 11 is "operable to," that is *capable of* halting pump operation, thereby isolating the filter 4 from the medical fluid supply 10. Applicant's claim limitations drawn to the operability of the device are held to be recitations of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. The Bene device, therefore, meets the limitations of the claims as presented.

9. With regard to applicant's arguments drawn to a bolus volume, applicant argues that Bene's distribution of fluid to the patient is not a bolus as claimed. However, the broadest reasonable interpretation of "bolus" is a dose of a substance given to a patient (see Merriam-Webster's Collegiate Dictionary, 10th Ed., 2001). Applicant has not set forth any difference between Bene's disclosure of administering a dose of fluid to the patient and the claimed "bolus volume." As such, Bene meets the limitations of the claims.

10. Applicant further argues that isolating the filter would destroy the Bene device. However, pump 11 may be stopped, thereby isolating the filter from the medical fluid supply, in the event that the patient does not require additional fluid infusion. Such pump stoppage and isolation would not destroy the Bene reference, since Bene specifically discloses that replacement fluid is delivered to the patient based on need. Therefore, the Bene device meets the limitations of the claims.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
21 August 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER